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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/776,309	02/11/2004	Dilip Tapadiya		3507
7590 07/08/2008				
DILIP TAPADIYA 4 TRAFALGER NEWPORT BEACH, CA 92660			EXAMINER KIDWELL, MICHELE M	
			ART UNIT 3761	PAPER NUMBER
			MAIL DATE 07/08/2008	DELIVERY MODE PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

### Office Action Summary

**Application No.**

10/776,309

**Applicant(s)**

TAPADIYA, DILIP

**Examiner**

Michele Kidwell

**Art Unit**

3761

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 09 April 2008.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 31, 32, 34-50 and 99-102 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 31, 32, 34-50 and 99-102 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SF/08)  
Paper No(s)/Mail Date \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: \_\_\_\_\_

## DETAILED ACTION

### *Claim Rejections - 35 USC § 103*

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 31 – 32, 34 – 47 and 99 – 102 are rejected under 35 U.S.C. 103(a) as being unpatentable over Olson (US 4,692,140).

With reference to claims 31 and 99, Olson discloses an irrigation kit comprising: a flexible sheet (40) having an aperture configured to engage an irrigation device (figures 2 – 3); and a basin for collecting irrigation fluid used during an irrigation procedure (col. 4, lines 35 – 39); wherein the aperture, in an enlarged state is configured to fit over a conical splash shield (end of element 20) extending distally from a collar (50) attached to a tip of the irrigation device (10) as set forth in the figures.

Alternatively, the examiner notes that the reference may be applied under a different interpretation with the flexible sheet being 30 and being configured to fit over element 40 which extends distally from collar 20 attached to a tip of the irrigation device 10.

The examiner recognizes that the Olson prefers a rigid material for element 30, but Olson teaches that the element 30 may be formed of any suitable material, which may include a flexible one, as set forth in col. 3, lines 60 – 66.

The difference between Olson and claim 31 is the provision that the basin is sterilized and made of a biocompatible hypoallergenic material.

It would have been obvious to one of ordinary skill in the art to sterilize the basin of Smith and produce it with a biocompatible hypoallergenic material since the purpose of the invention is to provide a safe environment for the collection of bodily fluids (col. 1, lines 6 – 34).

Likewise, it would have been obvious to one of ordinary skill in the art to provide the device with biocompatible, hypoallergenic material in order to prevent an undesirable reaction between the patient and the product.

As to claim 32, in view of the alternate interpretation used in the rejection of claim 31, Olson discloses a cannula (40) that includes an adhesive portion as set forth in col. 46 – 49. The examiner recognizes bonding as a form of adhesion.

Regarding claim 34, Olson discloses a flexible sheet including polyvinyl chloride as set forth in col. 3, lines 50 – 53.

With reference to claims 35, 37 – 38 and 101, see figure 2.

The difference between Olson and claim 36 is the provision that the flexible sheet has a specific thickness.

Olson discloses a flexible sheet that would ultimately have a thickness.

It would have been obvious to one of ordinary skill in the art to modify the thickness of Olson in order to determine the most effective product since Olson teaches the modification of such to provide a desirable product (col. 5, lines 41 – 43) and since it has been held that where the general conditions of a claim are disclosed in

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the prior art, discovering the optimum or workable range includes only a level of ordinary skill in the art.

As to claims 39 and 102, see the rejection of claim 36.

With reference to claims 40 – 42 and 100, Olson discloses that the shield 40 is made of a pliable latex material (polyvinyl chloride) that enables the element to be flexible and easily shaped as set forth in col. 3, lines 50 – 51.

While there is no explicit teaching of a specific elastic member, the examiner contends that the pliable latex material may function as an elastic member is certainly elastically deformable.

Regarding claims 43 – 47, the examiner contends that the use of the basin may be considered to be configured to collect fluid from any body part.

Claims 48 – 50 are rejected under 35 U.S.C. 103(a) as being unpatentable over Olson (US 4,692,140) in view of Holloway et al. (US 5,381,562).

The difference between Olson and claim 48 is the provision that the basin further comprises a grommet.

Holloway teaches a basin that comprises a grommet (84) as set forth in figure 6.

It would have been obvious to one of ordinary skill in the art to modify the basin of Olson to provide one with a grommet because the use of a grommet encourages a liquid tight sealed relationship as taught by Holloway in col. 7, lines 14 – 20.

With respect to claims 49 and 50, see the rejection of claim 31. Additionally, Holloway teaches a basin including a frangible, convertible portion as set forth in col. 7, lines 39 – 52.

***Response to Arguments***

Applicant's arguments filed April 9, 2008 have been fully considered but they are not persuasive.

With respect to the applicant's argument that Olson fails to teach a flexible sheet, the examiner disagrees. As set forth in col. 3, lines 50 – 51, Olson discloses the element 40 to be made from a pliable and flexible material. Likewise, the flexible sheet is fully capable of performing the recited function (i.e., being configured to fit over another element).

***Conclusion***

**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michele Kidwell whose telephone number is 571-272-4935. The examiner can normally be reached on Monday thru Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Tatyana Zalukaeva can be reached on 571-272-1115. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Michele Kidwell/  
Primary Examiner, Art Unit 3761